

5720.2REV2CoopInspectionPrograms7/24/92

REVISION 02 07/24/92

OPI: IO/FSR
PART 1 OF 7

COOPERATIVE INSPECTION PROGRAMS

PART ONE -- BASIC PROVISIONS

I. PURPOSE

The purpose of this transmittal is to provide information on the reissuance of FSIS Directive 5720.2, Rev. 2. This directive is intended to:

A. Be a single source of information on the policies and procedures for the management and administration of the State-Federal and Federal-State Cooperative Inspection Programs, including cross-utilization requirements, training, and qualifications.

B. Introduce the revised policies and procedures for the Federal-State Cooperative Inspection Program (commonly known as the Talmadge-Aiken Program).

II. CHANGE

A. Remove the following directives:

1. FSIS Directive 5110.4, Rev. , dated 9/24/91;
2. FSIS Directive 5720.2, Rev. 1, dated 10/30/87; and
3. FSIS Directive 5730.1, dated 4/7/86.

B. Extensive revision, retitling, and subject matter changes have been made. The FSIS Directives cited for removal have been consolidated into this new revised directive and new program policies have been incorporated.

III. ACTION REQUIRED BY PART III OF THE DIRECTIVE

A. Qualified States. Under the terms of this directive affecting the Federal-State Cooperative Inspection Program, State officials who commit less than 10 inplant staff-years to the program are required to inform the appropriate FSIS Regional Director of (1) their intention to continue operating under the provisions of the Federal-State Cooperative Inspection Program or request, (2) their plan to switch to a cross-utilization agreement with FSIS. The Regional Director must be notified in writing of the State's intention within 30 days after the effective date of this directive.

B. States Choosing Cross-utilization. A qualified State may make a one-time written request to the Regional Director to staff selected plants under a cross-utilization agreement. Under such an agreement, the state would be reimbursed at the rate of 100 percent. The effective date of such an arrangement would be mutually agreed to by the Regional Director, Area Supervisor(s), and State Program Director.

C. States Continuing to Operate a FSCIP. States that qualify for cross-utilization but that continue to operate a FSCIP and States that are not eligible to be considered for cross-utilization (i.e., that supply 10 or more inplant staff-years to the program) should implement the provisions of the directive as soon as possible. Essential steps include naming the Program Coordinator (PC) and making any necessary training or personnel changes. When the PC has been appointed and the State is ready to operate under the terms of the Directive, the actual implementation date is to be agreed on by the Regional Director and the Area Supervisor. It is the goal of the FSIS to have the changes fully implemented in all States no later than one year after the effective date of this directive.

D. States That Do Not Now Qualify for Cross-utilization. States that do not currently qualify for cross-utilization, i.e., that have committed 10 or more inplant staff-years to the FSCIP, may request that their program be converted to a cross-utilization agreement whenever the personnel requirements for their program fall below 10 inplant staff-years. Such requests must be submitted in writing to the Regional Director and will be considered case by case.

IV. CANCELLATION

Users may keep this transmittal in their records or destroy it when this directive has been filed and FSIS Directive 5110.4, Rev. 1, and FSIS Directive 5730.1, Rev. 1, have been removed.

Kenneth O. McDougall/for
Deputy Administrator
Inspection Operations

I. PURPOSE

This directive sets forth the policies and procedures relating to management and administration of the State-Federal, Federal-State, and Cross-Utilization cooperative inspection programs.

II. CANCELLATIONS

FSIS Directive 5110.4, Rev. 1, dated 9/24//91.
FSIS Directive 5720.2, Rev. 1, dated 10/30/87.
FSIS Directive 5730.1, Rev. 1, dated 4/7/86.

III. REASON FOR REISSUANCE

Extensive revision, retitling, and subject matter changes have been made. The directives cited under "Cancellations" have been consolidated and new program policies have been incorporated.

IV. REFERENCES

FMIA
PPIA
Talmadge-Aiken Act
Intergovernmental Cooperation Act
Federal Grant and Cooperative Agreement Act

MPI regulations
MPI Manual
FSIS Directive 1060.1, dated 11/5/86
FSIS Directive 3300.1, dated 10/3/80 (2 Amendments)

V. ABBREVIATIONS AND FORMS

CIP Cooperative Inspection Program
EEO Equal Employment Opportunity
FSIS Food Safety and Inspection Service
FMIA Federal Meat Inspection Act
FSR Federal-State Relations
IO Inspection Operations
MPI Meat and Poultry Inspection
NFC National Finance Center
OGC Office of the General Counsel
PC Program Coordinator
PPIA Poultry Products Inspection Act
SD State Program Director
SPP State Performance Plan
T&A Time and Attendance Report
TDD Training and Development Division
VMO Veterinary Medical Officer
WAE When Actually Employed

FSIS Form 3420-2, Billing Invoice
FSIS Form 5110-1, Services Rendered
FSIS Form 5720-1, State Training Report
FSIS Form 5720-2, State Laboratory Activity Report
FSIS Form 5720-3, Compliance and Inplant Activity Report
FSIS Form 5720-4, State Establishment Report
FSIS Form 5720-5, State Employment Report
FSIS Form 5720-6, State Slaughter and Processing Report
FSIS Form 5720-7, State Establishment Directory
FSIS Form 5720-8, State Review and Certification Summary
FSIS Form 5720-9, SPP Documentation Worksheet
FSIS Form 5720-10, Records Documentation Worksheet
FSIS Form 8110-2, Establishment Review and Assessment Worksheet
SF-269, Financial Status Report

VI. POLICY

A. The State-Federal Cooperative Inspection Program will be carried out under the authority of the FMIA and PPIA. USDA will provide oversight through the specific strategies outlined in Part Two of this Directive.

B. USDA will make use of the Federal-State Cooperative Inspection Program (FSCIP), as authorized by the Talmadge-Aiken Act, when it is deemed to be in the interest of the Department to do so.

C. FSIS recognizes the advantages for economy and efficiency of utilizing State personnel in the performance of mandatory and voluntary meat and poultry inspection functions in Federal plants. The cross-utilization of

employees to avoid dual staffing is to be undertaken to the greatest feasible extent, consistent with good management practices and effective use of personnel. The degree of cross-utilization between State inspection services and FSIS is to be reviewed and determined on a case-by-case basis.

D. The training requirements for State programs must be flexible enough to allow for the varying needs of individual States while allowing the States the opportunity of planning and developing training programs that are "at least equal to" those provided for employees in the Federal meat and poultry inspection program.

E. The Federal requirements for ethics and conduct are covered in detail in conditions for employment. It is expected that the States will meet requirements equal to those of the Federal requirements in State-Federal programs, and the same as in Federal-State programs.

F. The qualification for custom exempt status is defined in the Federal regulations, and the review of custom exempt operations is covered in FSIS Directive 5930.1, Revision 1, dated 6/27/90. This Directive requires that the Federal review of such operations be done on a frequency based on risk. States are expected to use the same criteria for such reviews.

G. Contract veterinarians employed by the States in supervisory or inplant VMO functions are to have training equivalent to that required for Federal veterinarians in similar positions.

H. No contract veterinarian may be employed for the purpose of making veterinary dispositions in those instances where a conflict of interest might arise. Conflict of interest is covered explicitly in Federal employment rules. For State inspection programs to be considered "at least equal to" the Federal program, similar prohibitions of conflict of interest must be enforced.

VII. DEFINITIONS

A. Acts means the FMIA and PPIA.

B. Call letter is the annual written communication to an organization requesting specific information on budgetary needs for the impending Federal fiscal year.

C. Basic Items are the requirements that are used to determine the classification of the State program.

D. Federal-State Cooperative Agreement is a document which provides for cooperation with a State agency according to the provisions of the Talmadge-Aiken Act (7 U.S.C. 450) for the use of State employees and facilities in carrying out Federal functions under the FMIA and PPIA. This document is not to be confused with the State-Federal Cooperative agreement defined below in paragraph K.

E. Federal-State Cooperative Inspection Program (FSCIP) means the activities carried out by FSIS and a State under the terms of a Federal-State cooperative agreement. Such an agreement sets forth the terms under which the Administrator of FSIS is authorized to utilize the employees and

facilities of the State in carrying out Federal functions under the FMIA and PPIA. The Federal-State Cooperative Inspection Program is not to be confused with the State-Federal Cooperative Inspection Program defined below in paragraph L.

F. Head of State Agency refers to the person (Commissioner, Director, Secretary, Chairperson) or delegate of such person who is in charge of the State Agency having jurisdiction over the meat or poultry inspection program of the State.

G. Regional Director; Deputy Administrator, IO; Assistant Deputy Administrator, Compliance Program; Director, FSR/IO refer to the persons occupying the positions or anyone who has been delegated the authority to act on their behalf.

H. Regulations means the Federal Meat and Poultry Products Inspection Regulations (9 CFR 301 et seq. 381 et seq.

I. Reviews means review activities which may include one or all phases of a State program ranging from reviews of records and reports to inplant reviews.

J. State means any State or organized territory of the United States, including the Commonwealth of Puerto Rico.

K. State-Federal Cooperative Agreement is a document which provides for cooperation with State agencies according to the provisions of Section 301 of the FMIA and Section 5 of the PPIA. This document is not to be confused with the Federal-State Cooperative Agreement defined above in paragraph D. A State-Federal cooperative agreement may provide for Federal advisory, technical, laboratory, training, and financial assistance for the development and administration of State meat and poultry products inspection programs, with a view to assuring that requirements that are at least equal to those of the Federal meat and poultry inspection program are imposed and enforced. Such cooperation is authorized if the State has enacted legislation governing the inspection of meat or poultry distributed in intrastate commerce that is at least equal to the Federal legislation governing the inspection of meat and poultry to be distributed in interstate commerce.

L. State-Federal Cooperative Inspection Program means the activities carried out by FSIS and a State under the terms of a State-Federal cooperative agreement. Such an agreement sets forth the terms under which the Administrator of FSIS is authorized to provide advice and assistance to the State in carrying out a meat or poultry inspection program that is at least equal to the Federal MPI program. The State-Federal Cooperative Inspection Program is not to be confused with the Federal-State Cooperative Inspection Program defined above at paragraph E.

M. State Performance Plan is a document that provides information on the organization of a State inspection program and procedures that will be used to ensure that the State inspection program is at least equal to the requirements contained in the FMIA and the PPIA.

N. State Program Coordinator refers to the person or delegate of such person who is responsible for the day-to-day supervision of State employees assigned under the FSCIP and regulatory management of FSCIP plants, and who

receives program direction from the Federal Area Supervisor. If the PC and SD are the same person, the PC is also responsible for the administration, regulatory management, and supervision of all State employees and FSCIP plants.

O. State Program Director refers to the person or delegate of such person who is directly responsible for the State meat or poultry inspection program.

P. Verification Review means a review conducted by State officials to prove that reviews performed by their personnel have been accurately performed, that the true condition of establishments is reflected through such reviews, and that any corrective actions have been taken as necessary.

PART TWO -- STATE-FEDERAL COOPERATIVE INSPECTION PROGRAM

I. ELIGIBILITY

The FMIA and PPIA permit the Secretary of Agriculture to cooperate with a State in developing and administering an inspection program which is "at least equal to" the Federal inspection program.

II. REIMBURSEMENT

The FMIA and PPIA require that the amount contributed to any State shall not exceed 50 percent of the total cost and the Federal funds shall be allocated among the participating States on an equitable basis.

III. PROGRAM MANAGEMENT AND ADMINISTRATION

A. General

The State Agency assigned the responsibility for administering the State's meat and poultry inspection program shall be responsible for carrying out the cooperative requirements of the FMIA and PPIA.

B. Maintaining the Integrity of the Slaughter Inspection Program.

Federal livestock and poultry slaughter inspection operations are carried out under the direct oversight of qualified veterinary medical officers (VMO's). Because of the impracticability of formulating rules covering every case and of designating at just what stage a disease process or condition results in adulteration of a product, it is necessary that the final inplant decision on the disposition of all carcasses, organs, or other parts, be left to the VMO. The VMO must exercise his or her judgment in the disposition of carcasses and parts in a manner that will ensure that only wholesome, unadulterated product is passed for human food. Veterinarians employed by the States, whether as permanent employees or on contracts for a limited duration, must be at least as qualified as Federal VMO's in making veterinary dispositions on meat or poultry carcasses and parts, whether the product is inspected under a State "equal-to" inspection program for intrastate commerce, or whether the product is prepared and inspected for distribution in interstate commerce.

C. Maintaining the Integrity of the Processing Inspection Program.

1. Federal meat and poultry processing inspection operations are carried out by qualified processed food inspectors under the oversight of supervisory processed food inspectors, food technologists, and VMO's. They are responsible for assuring that meat and poultry food products entered in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. While there are different manufacturing requirements and inspection criteria for each class of processed product, inspection is carried out to ensure that sanitation is adequate, approved formulations are followed, only wholesome ingredients are used, products are made in accordance with approved production procedures, and products are truthfully labeled. Inspectors have the authority to prevent adulterated products from entering commerce and to condemn any such products they discover at a processing facility.

2. Processing inspection personnel employed by the States must be at least as qualified as Federal employees to make inspection decisions on processed products, whether the products are inspected under a State "equal-to" inspection program, or under Federal jurisdiction for distribution in interstate commerce.

D. The Head of State Inspection Program Shall:

1. Prepare and submit the SPP to the Director, FSR/IO.

2. Prepare and submit updates as deemed necessary by the State, or required by the Deputy Administrator, IO.

3. Ensure that the SPP is adhered to and meets the Basic Items as described in Section IV, part B.

4. Furnish information and reports as outlined in Part 8 or otherwise required by FSIS.

E. The Regional Director, utilizing personnel located at the region, area, circuit and plant levels shall provide:

1. Pursuant to the Cooperative Agreement, technical, advisory and training assistance to State inspection programs within the region.

2. Counsel, as requested by the State, in preparing the SPP, call letter and other items.

3. Intra-regional communication to assure uniformity in the application of this Directive.

4. Personnel, as requested, to conduct oversight activities.

5. Input to the Director, FSR/IO, concerning operation of State program, type and depth of oversight activity required and the classification of the State inspection program.

F. The Director, FSR/IO, shall coordinate all FSIS activities involving State inspection programs and after consulting with other FSIS personnel

shall review and recommend to the Deputy Administrator, IO, the:

1. Classification of State inspection program.
2. Approval/disapproval of SPP.
3. Type of oversight activity required.
4. Composition of the review team that will perform oversight activities relating to the State inspection program.

G. The Deputy Administrator, IO, shall:

1. Approve or disapprove the SPP.
2. Provide for communication among FSIS, IO regional offices to promote uniformity in the application of this Directive.
3. Issue annual notification on the adequacy of the State program in meeting the at-least-equal to requirements of the FMIA and PPIA.

H. The Deputy Administrators, FSIS; Assistant Deputy Administrator, Compliance Program; and Staff Directors of Information and Legislative Affairs, Policy Evaluation and Planning Staff, and Equal Opportunity and Civil Rights Staff, shall provide:

1. Cooperation and coordination with FSR/IO in the development of oversight activities relating to State inspection programs.
2. Personnel to conduct oversight activities relating to State inspection programs.
3. Pursuant to the Cooperative Agreement, technical, advisory and training assistance to State inspection programs.
4. Input to the Director, FSR/IO, concerning type and depth of oversight activities required and the classification of the State inspection program.
5. Uniform application of program standards between the Federal and State inspection programs.

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IV. STATE PERFORMANCE PLAN

A. General. Each State that operates a meat or poultry inspection program must submit an SPP. The plan must describe the operating practices

and procedures used by the State for administering and managing its inspection system within the context of the Nine (9) Basic Items defined in the following Section (B).

B. Basic Items. The following are Basic Items for evaluating State meat and poultry inspection programs:

1. Laws. State law must be at least equal to the FMIA and PPIA by granting authority for the development, administration and enforcement of the State meat and/or poultry inspection program.

2. Regulations. The State inspection program must promulgate regulations at least equal to the Federal regulations.

3. Funding and Financial Accountability. The State must appropriate funds commensurate with those provided by the USDA as specified by the Cooperative Agreement. Follow fiscal guidelines as contained in FSIS Directive 3300.1 and budgetary requirements as contained in the annual FSIS call letter.

4. Resource Management. The State shall maintain records and information and shall outline procedures for determining the level and type of resources required in the following areas:

a. Staffing. Having enough employees to carry out the responsibilities assigned to all organizational levels, units and functions.

b. Training. Providing directly or contracting for employees, the technical, professional, administrative, supervisory, and managerial training required to maintain a competent and productive workforce.

c. Program Operations. Maintaining records and reports that explain the full range of the activities and administration of the State inspection program.

5. Facilities and Equipment. The State shall have a system for reviewing and approving blueprints for new construction or remodeled facilities and equipment that is at least equal to USDA standards.

6. Labels and Standards. The State must have a system for approving labels to assure accurate labeling of all products at least equal to USDA standards and developing accurate labeling for new or specialty items not covered by USDA standards.

7. In-plant Reviews/Enforcement.

a. The State must have a system of in-plant reviews to assure that slaughtering and processing inspection activities are conducted in accordance with USDA requirements. The Review and Evaluation Glossary and Format in FSIS Directive 8110.2 should be used as a guide.

b. The State must have a system comparable to USDA requirements for monitoring plants which are exempt from inspection requirements.

c. The State must have an enforcement system for detecting violations, and investigating and enforcing State meat and poultry laws. Enforcement includes all activities to correct deficiencies inside and outside plants.

8. Specialty Programs. The State must have an adequate residue monitoring and control program. Also the State must have programs (protein-fat-free, species determination, etc.) which may be addressed through participation in the current USDA program or by developing and conducting its own specialty programs that are at least equal to USDA requirements.

9. Laboratories. The State must utilize laboratories with analytical capabilities comparable to those of FSIS laboratories. The laboratories must be able to perform tests to determine product wholesomeness and compliance with regulatory standards, and employ experts in the disciplines of chemistry, microbiology and pathology. Such laboratories may be:

a. State Laboratories

b. Private Laboratories (including laboratories accredited by FSIS).

c. USDA Laboratories. State and private laboratories must be FSIS-accredited or participate in the check sample program conducted by FSIS or in chemistry check sample programs which may be approved by FSIS.

C. Submission of State Performance Plan.

1. The CIP States are to submit a SPP to the Deputy Administrator, IO/FSIS, for approval. Once the SPP is approved, it must be kept up to date to reflect any subsequent changes. The SPP and changes thereto must address the 9 Basic Items outlined in Part II, Section IV, par. B, of this Directive.

2. Each SPP must be submitted with a transmittal cover sheet using the format described in Attachment 2-1.

D. Suggested Format.

1. Laws.

a. Identify Titles, Chapters, and Sections of the State laws which are applicable to the inspection program.

b. If the laws have not been previously approved by USDA, a copy should be submitted with the SPP for approval.

2. Regulations.

a. Identify Titles, Chapters and Sections of the State regulations which are applicable to the inspection program.

b. If the Regulations have not been previously approved by USDA, a copy should be submitted with the SPP for approval.

3. Funding and Financial Accountability. As required by the Cooperative Agreement and as outlined in FSIS Directive 3300.1:

a. Submit the Federal budget request(s) to FSIS.
b. Describe the State budget process. Include dates and the current status of State funding.

c. Describe the procedures for maintaining accountability of the receipt and expenditure of Federal funds for MPI.

d. Describe the procedures for maintaining accountability of the receipt and expenditure of State funds for MPI.

e. Describe the audit process used.

4. Resource Management.

a. Staffing .

(1). Describe the organizational structure. (If necessary, include organizational chart to clarify.)

(2). Describe the staffing patterns, positions, position titles and minimum qualifications for the field for each geographical jurisdiction. (List and identify personnel assigned to compliance and enforcement activities.)

b. Training. Describe the duration, frequency, mode and type of training resources for each of the following categories:

(1). Newly Hired Personnel.

(2). Supervisors.

(3). Staff and Professional Development.

(4). Continuing Education Programs.

c. Program Operations. Describe State records of the operation and administration of State inspection program that are not provided for elsewhere in the plan. (Example: What information is available to describe the activities, accomplishments, and goals of the program?)

5. Facilities and Equipment.

a. Identify staff position(s) responsible for approving the facilities and equipment program.

b. Describe the standards and procedural requirements for facility, equipment and blueprint approval.

c. Identify what organizational levels review or approve the equipment and blueprints.

d. Describe any variations to FSIS Directive 11,140.1, also known as USDA Handbook 570, "U.S. Inspected Meat and Poultry Packing Plants, A Guide to Construction and Layout," and to FSIS Directive 11,220.1, also

known as MPI-2, "Accepted Meat and Poultry Equipment."

e. Describe the recordkeeping system used for equipment and blueprint approval.

6. Labels and Standards.

a. Identify staff position(s) responsible for approving labels.

b. Describe the system used for approval, control and maintenance of labels.

c. Describe the system used for development and maintenance of meat and poultry standards.

d. Describe any exceptions from FSIS label approval system and the published standards.

e. Describe the State program controls of official and/or restricted devices.

7. In-Plant Review/Enforcement.

a. In-Plant Review.

(1). Format. Describe any exceptions or modifications to the Review and Evaluation Glossary and Format as outlined in FSIS Directive 1060.1.

(2). System.

(a). Identify, by position and title, the person responsible for selecting, scheduling, and correlating State plant reviews.

(b). Identify positions within the State program that are responsible for conducting State in-plant reviews.

(c). Indicate the frequency that each official State plant will be reviewed.

(d). Describe the internal program used to ensure the validity of official State plant reviews.

(e). Describe the recordkeeping system used for official State plants and verification reviews.

(f). Describe the system for monitoring State plants which are exempt from inspection requirements.

(3). Follow-up and Corrective Action.

(a). Describe the procedures used for follow-up and corrective action.

(b). Identify the levels of the organization responsible

for the follow-up action.

b. Enforcement Activities

(1). Describe the organization of compliance activities, such as surveillance, evaluation, investigation, and enforcement duties which are not assigned exclusively to inplant or administrative personnel.

(2). Describe any exceptions or modifications to the current Federal Enforcement Program as described in FSIS Directive 8070.1.

(3). Describe the recordkeeping system used for the State Enforcement Program, if not described elsewhere.

(4). Describe the system used in disposing of meat and poultry products, in distribution channels, that are found to be in noncompliance, if the system is not described elsewhere.

8. Specialty Programs.

a. Describe the system used for approving and monitoring each specialty program, such as programs for residues and PFF.

b. List any exceptions or additions to the "List of Proprietary Substances and Nonfood Compounds" used in meat or poultry plants.

c. Identify any on-site tests used for disposition of carcasses or product.

9. Laboratories
(Chemical/Microbiological/Pathological).

a. Analyses.

(1). Indicate the name, address and type of laboratory conducting the analyses.

(2). Describe the types of analyses conducted.

(3). Describe the methodology used and, if not available through publication, submit a copy for review.

(4). Describe the Quality Assurance Program that the laboratories use for each type of analysis and procedures followed in taking corrective action (FSIS check sample, etc.). (Example: How does the State ensure that laboratory personnel are running tests correctly and what actions are taken to correct deficiencies?)

b. Describe the recordkeeping system used by the laboratory.

c. Describe procedures used for controlling program or compliance samples that may result in litigation.

E. Maintenance Requirements.

1. General. After the initial submission and approval of the SPP,

the Head of the State inspection program is responsible for keeping the SPP up to date. The SPP must be revised on the basis of new or modified requirements that are submitted, in a timely manner, as amendments to the initially approved SPP.

2. Transmittal. The cover letter used to transmit changes to the State SPP shall summarize the changes.

3. Submission. Submit seven copies of changes to the SPP as follows:

a. Six copies to:

Director, Federal-State Relations
Meat and Poultry Inspection Operations
Food Safety and Inspection Service,
USDA
Room 4865, South Building
Washington, DC 20250

b. One copy to the appropriate FSIS Regional Director.

V. OVERSIGHT STRATEGIES

FSIS will employ three strategies for conducting oversight reviews:

1. Strategy 1. The review of the State Performance Plan, related reports, and information derived from various sources.

2. Strategy 2. Strategy 1 and the results of a special review of the State's inspection program.

3. Strategy 3. Strategy 1 and the results of a comprehensive review of a State's overall inspection program.

VI. ANNUAL CERTIFICATION

FSIS will follow one or more of the oversight strategies described above for each participating State. After considering the results of the oversight activities described above and the Annual Review of Program Performance described in Part Nine of this directive, the Agency will, at the end of the Federal Fiscal Year, give the State a certification of "meets" or "does not meet" the "at least equal to" requirements.

VII. COMPREHENSIVE REVIEW

A. General. The primary purpose of the comprehensive review is to determine if a State's inspection program is "at least equal to" that of the Federal program. This determination is based on the evaluation of the State with respect to the nine basic items described in Section IV, paragraph B. The procedures established for making an "at least equal to" determination are based on the notion that an inspection program is comprised of various systems and processes that must be viewed in their totality before the adequacy of a State's program can be determined. Within this framework, the

following principles of organizational management systems and performance are essential to successful State inspection programs:

1. The States must have written standards and procedures in place, and they must clearly outline the responsibilities and authorities of the inspection officials at all organizational levels - headquarters through plant.

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2. The employees responsible for carrying out the procedures and standards must be qualified to do so.

3. A process must be in place for overseeing inspection operations to determine if they are working properly with respect to policy, procedure, or performance.

4. There must be a corrective action process to be initiated when deficiencies are found. Also, there must be a means of obtaining evidence at the plant level that the process is working correctly.

The mechanism for deciding how well a State's inspection program is functioning consists of (1) determining adherence to the Performance Plan (SPP), (2) the review of records, and (3) the review of inplant conditions and operations. The results of these activities, governed by the above principles, enable FSIS officials to determine the "at least equal to" status of a State program. A State's SPP will be subject to a total review, whereas records and inplant conditions and operations will be reviewed on the basis of a statistical sample of the affected population.

B. Purpose of the Review Activity. To ensure that the SPP is being followed and is effective, and that the State is maintaining a program at least equal to the requirements in the FMIA and PPIA and MPI Regulations, the reviews will be made to:

1. Determine findings and actions of State personnel.
2. Determine if actions were correct and appropriate and solved the problem.

3. Determine if the State is following procedures contained in the SPP.

C. Review Criteria.

In addition to the SPP, reviewers conducting reviews of records and reports will evaluate:

1. Routine Operations.

- a. Laws. Determine that laws are up to date. If reviewers are in doubt, they are to submit copies to the Director, FSR, for review and consultation with OGC.

- b. Regulations. Determine that regulations are up to date. If reviewers are in doubt, they are to submit copies to the Director, FSR, for review and consultation with OGC.

- c. Funding. Ensure adequate budgeting.

- d. Resource Management. Ensure that staffing, training, financing, operational evaluations and reviews, policy formulation, and procurement are adequate and support the "equal to" status of the program.

- e. Facilities and Equipment. Determine that blueprint and equipment submittals are properly approved and maintained.

- f. Labels and Standards. Determine that labels and product standards are properly approved and maintained.

- g. Inplant Review and Enforcement. Determine that slaughter and processing procedures, sanitation, plant improvement plan, laboratory sample system and results, reviews (routine, supervisory, and verification), follow-up of corrective actions, and enforcement activity are adequate.

- h. Specialty Programs. Determine the adequacy of sample results, and determine that action to correct deficiencies is appropriate.

- i. Laboratory. Determine that the laboratory has proper control of samples and quality control results, and that actions to correct deficiencies are appropriate.

2. Reports Required by FSIS. See Part Eight of this Directive.

- D. Review Team and Types of Reviews.

1. Review Team.

- The review team will be led by the Deputy Regional Director, the Team Leader, and will be composed of Agency officials representing various functional areas. The team will always include subject matter experts in operations, budget and finance, resource management, and compliance, and will sometimes include experts in chemistry and equal employment opportunity and civil rights.

2. Plant Records.

- a. The type of records to be reviewed will depend on the purpose of the review. The number of establishments to be randomly selected for review of records and whose records are to be reviewed depends on the number of inspected plants in a State as shown in the chart in Attachment 2-4.

- b. Randomly select the plants whose records are to be reviewed.

In addition, randomly select at least one custom-exempt plant for records review. All plant records reviewed must be acceptable to FSIS. If they are not, the Team Leader will consult with the Director, FSR/IO.

c. After consulting with the Director, FSR/IO, the Team Leader may decide to select additional plants for records review. This decision will be based on the results of the records review for the initial selection of plants or on other information. The additional plants need not be randomly selected.

3. Plant Visits.

a. Plants will be visited to ensure that they are in compliance with the SPP and that the plant records accurately depict the conditions and operations of the plant. The visits will also be made for the purpose of verifying the adequacy of State inplant reviews and enforcement activities.

b. The plants to be visited will be randomly selected from among those whose records have been reviewed. The number of plants to be visited will be determined by consulting the chart in Attachment 2-5. The column labeled "No. of Official Plants" will be interpreted to mean the number of plants whose records have been reviewed. Findings in all plants must be acceptable to FSIS. If not, contact the Director, FSR/IO.

c. After consulting with the Director, FSR/IO, the Team Leader may decide to visit additional plants. This decision will be based on the results of plant visits already made or on other information. The additional plants need not be randomly selected. In addition to the official plants, at least one custom-exempt plant must be reviewed.

E. Frequency.

As stated in Part Two, IO will conduct a periodic comprehensive review of each State inspection program. Comprehensive reviews will be conducted according to the category assigned to the State inspection program as a result of the last comprehensive review.

1. Category 1 - Acceptable (At Least Every 5 Years). All required items are in compliance with the Acts, Regulations and SPP.

2. Category 2 - Acceptable with Minor Variations (At Least Every 4 Years).

a. Variations found during reviews were considered minor and do not affect public health.

b. Possibility that adulterated or misbranded product could enter human food channels is minimal.

c. Procedures in the SPP are being followed and updates are being sent to FSIS officials.

d. Corrective actions taken by State officials were adequate to assure program maintenance in full compliance with the Acts and Regulations.

3. Category 3 - Acceptable with Significant Variations (At Least Every 3 Years)

a. Variations found during reviews were considered significant and may affect public health but were corrected immediately.

b. Possibility that adulterated or misbranded product can enter the human food channels is minimal.

c. Procedures in SPP are being followed but effectiveness is in question.

d. Changes have been made in SPP but updates have not been sent to FSIS officials as required.

e. Actions taken by State officials are less than adequate to assure that the program is maintained in compliance with the Acts and Regulations.

4. Category 4 - Unacceptable (Frequency to be based on the nature of unacceptable findings).

a. Variations found during reviews were considered significant and which may affect public health and were not corrected.

b. Possibility that adulterated or misbranded product has entered or can enter human food channels.

c. Procedures in the SPP are not being followed, or procedures are being followed but are not effective.

d. Major procedures in the SPP have been changed but updates have not been sent to FSIS officials as required.

e. Actions taken by State officials are less than adequate to assure the program is maintained in compliance with the Acts and Regulations.

F. Schedule.

Each fiscal year, the FSR Director will schedule comprehensive reviews of States. Refer to paragraph V, above, for further discussion on oversight strategies.

G. Coordination.

Agency officials responsible for assigning reviewers are requested to do everything possible to meet the deadlines proposed by the FSR Staff in order to minimize revision of the review schedule. It is recognized that an Agency official with responsibilities in a subject matter area may want a particular State to be reviewed early in the process. If that is the case, the FSR Staff should be fully informed of the reasons why and every effort will be made to schedule the State for review at a time compatible with the requirements of the requesting official.

The Deputy Regional Director will serve as the Team Leader for all State Reviews. The Federal/State Relations Staff will facilitate the establishment of each review team by:

1. Talking with the heads of the various FSIS operations to determine the availability of personnel for the various subject matter areas.

2. Talking with the Deputy Regional Director, who is to determine the availability of, and arrange for, the appropriate number and types of personnel required to review inspectional aspects of the State's program.

3. Using the feedback received from persons in item 1. and 2., from the various FSIS operational heads and the Deputy Regional Director, to establish the review period after consulting with the affected State official.

4. Informing the Deputy Regional Director of the names of team members and dates of review. Attachment 2-1 to this document is a form letter which will be used for this purpose. Attachment 2-2 to this document is a form letter which the Deputy Regional Director will use to notify the reviewers.

H. Pre-Review and Exit Conferences.

1. The Team Leader will be responsible for opening and closing the review with the appropriate State official(s). The opening of the review may be handled either via telephone or at an on-site meeting. Factors to consider in deciding how the review should be conducted are: (1) size of the State program, (2) proximity of the regional office to the state office, (3) relationship of the date(s) of the inspectional review segment and start-up of the comprehensive review, and (4) cost. As particular subject matter experts start their review process, they are expected to handle their own pre-review meetings. It is at the option of the Team Leader to decide whether he will or will not participate in the various opening and closing meetings.

2. The Team Leader will conduct the exit conference with the head of the State inspection program. The program head's immediate superior and other State officials whose subject areas were reviewed should be encouraged to attend the conference.

3. The goals of the Exit conference are:

- a. To provide a forum for discussion of the review findings. In this portion of the exit conference, there should be allowance for give-and-take discussion of review findings. To improve the organization of such discussions, the Team Leader should have listed in outline form the major findings of the review, and have prepared sufficient copies of the outline for distribution among the attendees.

- b. To provide a list of items the State Director must response to, in writing, within 30 days after the exit conference. The outline referred to above serves very well for this purpose. In many instances, during the discussion of findings, some items may be stricken from the list upon mutual agreement that the issue is resolved, or was not an issue.

Conversely, the discussion may reveal that additional items need to be added to the list.